Rosin Esters - Environmental Defense Comments

(Submitted via Internet 8/5/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Rosin Esters.

The test plan and robust summaries for the rosin esters was prepared by the Pine Chemicals Association (PCA), which represents 25 companies. Test plans for rosin, rosin salts, and rosin adducts were previously submitted by the PCA. This test plan includes seven substances. Rosin is a complex mixture found primarily in pine trees and the rosin esters are made by reacting rosin with a variety of alcohols. Rosin esters are used in a variety of adhesive products and also in chewing gum, and are approved by FDA as a direct food additive.

The test plan was well organized and clearly justified for the most part. We commend the PCA on an excellent and informative document and we agree with the proposals contained in it with two exceptions as noted below.

Before discussing those exceptions, we note that we support the sponsor's selection of rosin pentaerythritol (RPE) and rosin partially hydrogenated methyl ester (RPHME) as the representative substances for this category. This is a good selection as these compounds represent the extremes of molecular weights for this category; thus, they most likely will bracket the toxic responses as well. RPE and RPHME will be tested for fish toxicity and all seven members will be tested for partition coefficients, water solubility and biodegradation except for RPHME where biodegradation studies are already available. Based on the lack of data in these areas, we support the testing proposals made by PCA.

However, we do not support PCA's proposals to conduct (i) acute toxicity testing on RPE or (ii) in vivo genetic toxicity testing for RPHME. With regard to the former, RPE has been subjected to both 90-day and lifetime cancer studies in rodents in which a maximally tolerated dose of 5000 mg/kg was established. No scientific information of public health value will be obtained from conducting an acute toxicity study on RPE, so such a study would be a needless use of animals. Similarly, we do not support the proposal to conduct in vivo genetic toxicity testing on RPHME. Under the HPV program, in vitro genetic toxicity methods should be used "unless known chemical properties preclude its use." That does not appear to be the case in this instance.

We support the sponsor's plans to test RPHME in a combined repeat dose/reproduction/development study. Such testing will appropriately addresses a significant data gap for this substance. RPE will be evaluated for developmental toxicity. With data from the proposed tests in hand, requirements for the HPV program will clearly be met. We note that existing data from long-term studies indicate that the rosin esters possess low toxicity and are they are likely not carcinogenic even at high doses. The read-across approach proposed by the PCA is scientifically justified.

Thank you for this opportunity to comment.

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